FEDERAL MINISTRY OF HEALTH

NATIONAL IMPLEMENTATATION GUIDELINE FOR TB PREVENTION AND CONTROL THROUGH PUBLIC-PRIVATE MIX APPROACH IN ETHIOPIA

December, 2017

Third Edition

ADDIS ABABA, ETHIOPIA

NATIONAL IMPLEMENTATATION GUIDELINE FOR TB PREVENTION AND CONTROL THROUGH PUBLIC-PRIVATE MIX APPROACH IN ETHIOPIA

December, 2017

Third Edition

ADDIS ABABA, ETHIOPIA

Table of Contents

ACKNOWLEDGEMENTS

The publication of third edition of this guideline is possible due to unreserved commitment by the Federal Ministry of Health (FMoH) and its partners to strength TB prevention and control responses in Ethiopia. Private Health Sector Project (PHSP/USAID) has covered the cost of this guideline finalization workshop. The development of the guideline was contributed by the following professionals who represented their organizations as follows.

Name	Organization
Dr. Abraham Alemayehu	NTP/FMoH
Dr. Yewulsew Kassie	USAID
Dr. Asfawessen Gebre yohannes	PHSP
Dr. Eshetu Gezahegn	PHSP
Dr. Aschalew Worku	ETS
Dr. Eshetu Kebede	WHO
Dr. Aynalem Abraha	FMHACA
Genet Mengstu	DHD
Dinsa Bedada	SC
Selamawit G/egziabher	ARRA
Gashanew Asrat	FMHACA
Wondimu G/Kiros	PHSP
Leulseged Takele	PHSP
Alemtsehay Berhanu	PHSP
Konjit Getahun	FPA
Mesfin Abera	PHSP
Solomon Sisay	GLRA
Kifle Sede	NTP/FMoH
Dr. Zewdu Gashu	CTB
Dagim Damtew	PLMU/FMoH
Zelalem Kebede	EPHFEA
Dr. Eshetu Abdissa	PHSP
Dr. Anteneh Kassa	NTP/PHSP
Mintesinot Nida	PFSA
Mohammed Dawd	PHSP
Etsegenet Getachew	NTP/FMoH
Tsige G/mariam	FPC
Dr. Tefera Girma	CDC
Tilaye Tassew	PHSP

FOREWORD

Ethiopia has reached considerable progress in tuberculosis prevention and control by expanding and use of high quality DOTS services as per WHO recommendations. Engagement of both public and private health care facilities through Public-Private Mix approach has significantly added on the TB prevention and control effort. PPM-DOTS Implementation Guideline in 2006 and its revised version in 2012 provided a formalized structure for engagement of PPM DOTS health care facilities.

Currently huge numbers of health care facilities are delivering health care services for sizeable proportion of population in the country. These health care facilities are owned either by private or public sector. Engaging these health care facilities in TB prevention and control activities would improve TB case finding and case holding, standard case management to reduce treatment errors and risk of drug-resistant TB, capacitate human resource base for NTP and reduce caseload for health sector.

According to 2017 national tuberculosis control program report, there are more than 800 health care facilities which are engaged in TB prevention and control services through PPM initiative. Currently these health facilities are contributing from 10.0% to 15.0% for national TB case detection. PPM-DOTS initiative has also been made growing ownership by political leaders, program implementers and managers in the country including assigned PPM initiative focal point and established PPM DOTS TWG.

Since 2012, several lessons have been learned through implementation of PPM initiative in the country. Moreover, the national and global TB prevention and control strategies are updated to incorporating new developments into PPM guideline to give direction on PPM DOTS execution. I hope this guideline will further strengthen the public private partnership efforts to fight against tuberculosis in Ethiopia.

Kebede Worku (MD, MPH)
State Minister for Health

ACRONYMS

ACSM	Advocacy, communication and social mobilization
AFB	Acid Fast Bacillus
ART	Anti-Retroviral Therapy
ARRA	Administration for refugees and returnees affair
CDC	Center for Diseases Control
CTB	Challenge TB
DHD	Defense Health Directorate
DOT	Directly Observed Therapy
DOTS	Directly Observed Treatment, Short course
DR-TB	Drug resistant tuberculosis
DST	Drug Susceptibility Test
EPHI	Ethiopia public health institute
EQA/QA	External Quality Assurance/Quality Assurance
ETS	Ethiopia Thoracic Society
FBOs	Faith Based Organizations
FMHACA	Food, Medicine and Healthcare Administration and Control authority
FMOH	Federal Ministry of Health
FPA	Federal Prison Administration
FPC	Federal Police Commission
GLRA	German Leprosy Relief Association
GTP	Growth and Transformation Plan
HEW	Health Extension Worker
HMIS	Health Management Information System
HIV	Human Immunodeficiency Virus
HSTP	Health Sector Transformation Plan
IC	Infection Control
IPLS	Integrated Pharmaceuticals Logistics System
IPT	Isoniazid Preventive Therapy
IQC	Internal Quality Control
ISS	Integrated Supportive Supervision
ISTC	International Standards for Tuberculosis Care
JSS	Joint supportive supervision
MDR-TB	Multi-Drug Resistant Tuberculosis

MOU	Memorandum of Understanding
NGO	Non-Governmental Organization
NTP	National Tuberculosis Control Program
NSP	National tuberculosis prevention and control strategic plan
PFSA	Pharmaceutical Fund and Supply Agency
PHSP	Private Health Sector Project
PLHIV	People living with HIV
PMDT	Programmatic Management of Drug Resistant Tuberculosis
PPM	Public-Private Mix
PPP	Public Private Partnership
PPPH	Public Private Partnership for Health
PSM	Pharmaceuticals Supply Management
QC	Quality Control
REQAS	Random External Quality Assurance System
RHB	Regional Health Bureau
RRF	Report and Requisition Form
SC	Sugar Corporation
SL-DST	Second line drug susceptibility test
SOP	Standard operating procedure
TB	Tuberculosis
TB/HIV	Tuberculosis and HIV Co-infection
TFC	Treatment Follow up Center
TIC	Treatment Initiation Center
THO	Town Health Office
TWG	Technical Working Group
WoHo	Woreda health office
WHO	World Health Organization
ZHD	Zonal Health Department

DEFINITION OF TERMS

Certification is the process by which the NTP officially documents that a PPM facility of any level has met the criteria to offer TB prevention and control services.

Decertification is the procedure under which a PPM health care facilities is withdrawn from implementing TB prevention and control service due to none adherence to the pre-agreed term or voluntary request by PPM health care facility.

Other governmental health facilities are health care facilities owned by government but administratively they are not under ministry of health structure

PPM DOTS stands for all types of TB prevention and control services as per the context in which it exists

PPM health care facilities are health facilities (Private for profit, Private for non-profit, other governmental or workplace health facilities) which are engaged in the provision of TB prevention and control services

Workplace health facilities are health care facilities which are mainly serving staff/family members of particular organization/company

1. INTRODUCTION AND BACKGROUND

Tuberculosis (TB) is a major public health problem throughout the world. About a third of the world's population is estimated to be infected with tubercle bacilli and hence at risk of developing active disease. According to the WHO Global TB Report of 2017, 10.4 million people are estimated to have fallen ill with TB in 2016 while an estimated 1.3 million people died of TB and an additional 374 thousands deaths resulting from TB disease among people living with HIV. Although the number of TB deaths fell by 35.0% between 2000 and 2016, TB remained one of the top 10 causes of death worldwide in 2015. Globally in 2016, an estimated 4.1% of new cases and 19.0% of previously treated cases had MDR/RR-TB and there were about 240 000 deaths from MDR/RR-TB. There are also the 30 high burden countries for TB, TB/HIV and MDR-TB that accounted for 80% of all TB cases worldwide.

Ethiopia is among the 30 high TB, TB/HIV and MDR-TB burden countries with an annual estimated TB incidence of 177/100,000 populations and death rate of 25 per 100,000 populations for 2016. Among the notified TB cases in 2015, 2.7% of new TB cases and 14% of previously treated TB cases were estimated to harbour MDR-TB. National DR-TB sentinel report in 2013 shows the MDR-TB prevalence of 2.3% among new TB cases and 17.8% among previously treated TB cases, which indicates increasing trends in TB drugs resistance burden compared to the first DRS survey conducted in 2003-2005. TB and HIV co-infection is an additional problem in the control of TB in the country whereby 8.0% of annually notified TB patients was found to have HIV co-infection.

In a major milestone for the history of TB control, in May 2014, the End TB Strategy was adopted by the World Health Assembly of WHO. The End TB Strategy highlights that if we continue with business as usual, ending the TB epidemic will remain a long distant dream. PPM DOTS initiative is something that cuts across the three pillars and the 10 components of the new strategy.

Though TB control efforts in Ethiopia have improved significantly in the past decade with the expansion of the Directly Observed Treatment Short-Course (DOTS) model; and TB prevalence and mortality rates have declined in recent years; there are still higher targets to be met. Ethiopia has achieved the millennium development goals for TB in 2015 and adopted new post-2015 Global TB Strategy called End TB strategy. This strategy aims to end the global TB epidemic with targets to reduce TB deaths by 95% and new cases by 90% between 2015 and 2035. The global strategy also targeted to ensure that no family is burdened with catastrophic expenses due to TB.

Both the WHO and the Federal Ministry of Health (FMOH) have long recognized that TB control is a challenge for public- health sector in high burden TB countries to manage effectively with its limited resources and coverage. In 2004, the WHO recommended widening of the scope of Public-Private Mix (PPM) to include all public and private health care facilities not formally linked to government-funded TB prevention and control programs. At the global level, a subgroup on PPM for TB care and control has been established as part of the Stop TB Partnership, to support the scale-up of PPM DOTS implementation. WHO further defined Public-Private Mix (PPM) for TB prevention and care as engaging all relevant health care providers in TB care and control through public-private mix approaches is an essential component of WHO's End TB Strategy. PPM for TB prevention and control represents a comprehensive approach for systematic involvement of all relevant health care providers in TB prevention and control to promote the use of International Standards for TB Care and achieve national and global TB control targets.

PPM encompasses diverse collaborative strategies to engage relevant health care providers through public-private (between NTP and the private sector), public-public (between NTP and other public sector care providers such as general hospitals, prison or military health services and social security organizations) and private-private (between developmental partners or private hospitals and the neighborhood private providers) partnerships to deliver standardized, high

quality TB care to all. PPM also implies engaging relevant care providers in prevention and management of multi-drug resistant TB (MDR-TB) and in the implementation of collaborative TB/HIV activities. In general, the National Tuberculosis and Leprosy Control Program considered PPM-DOTS as a way to expand these services since PPM initiative helps to address services tailored to drug susceptible TB, drug resistance TB and TB/HIV co-infected patients in the public and private settings.

PPM for TB prevention and control began in Ethiopia as a pilot program in Addis Ababa and Oromia in 2006 and shown significant contribution on TB case detection. Evidence indicates that PPM-DOTS health care facilities in the country had contributed to 13.0% of all forms of TB cases detected in 2016/17 and TB treatment outcomes in PPM-DOTS sites had shown comparable outcomes with public health facilities. By the end of 2017, the number of PPM-DOTS health care facilities throughout the country reached around 700 private, 130 other governmental and 50 workplace health care facilities. Recent TB program review showed that about 10.0% to 15.0% among newly detected TB cases were contributed by PPM TB care providers with similar TB treatment cure and completion rate as of NTP target.

The purpose of this implementation guideline revision includes providing updated direction in the implementation of PPM DOTS programs that is aligned with the national strategic plan and End TB strategy. The revised includes lessons learned and other operational insight gained from existing PPM-DOTS implementation experience. As with the previous guidelines, this implementation guideline is based on the principles of the International Standards for Tuberculosis Care (ISTC).

1.1 Rationale for strengthening PPM-DOTS in Ethiopia

Patients with symptoms suggestive of TB seek care from a wide array of health-care providers. These care providers, often not linked directly to NTP, may serve a large proportion of presumed TB cases. Evidence suggests that failure to involve all care providers used by TB suspects and patients hampers case detection, delays diagnosis, leads to inappropriate and incomplete treatment, contributes to increasing drug resistance and places an unnecessary financial burden on patients. A systematic involvement of all relevant health care providers in delivering effective TB services to all segments of

the population is essential to reach the 90-(90)-90 targets set up in the Global Plan and the End TB Strategy. It is clear that business as usual approach is no longer adequate to deal with fragmented and largely unregulated PPM healthcare providers in the country. The missing TB cases will remain invisible until the PPM health care providers are engaged to offer better quality care of persons with TB. It is important to explore PPM approach to engage all health care providers in TB prevention and control services scale-up effort.

PPM initiatives in a number of high TB burden countries have regularly demonstrated increased case notification and levels of treatment success equal to those seen in the effective public sector. In 2013, PPM health care providers contributed a significant proportion (up to 40%) of the notified TB cases in several countries or settings.

Ethiopia has designed a five-year national action plan for PPM-DOTS as part of NSP. The goal of the national PPM action plan is to accelerate the pace of PPM health care providers' engagement to increase their TB case notification contribution to 26.0% of national TB program performance and to support national NSP target achievement by 2020.

In Ethiopia, PPM health care providers' contribution to annual TB case notifications ranges 10.0% to 15.0%. Engagement of the private health facilities in the delivery of TB services is a key mode of expanding available and standardized TB prevention, care and treatment promoted by the WHO. In Ethiopia, there is a strong political commitment to engage the private health sector to contribute to the health care delivery system of the country. Growing interest within the private health sector in health investments have created an enabling environment for public-private partnership. In the last couple of years, the private health facilities have flourished and there are more than 12,000 private facilities in the country. Coherently other governmental and workplace health facilities have shown growing interest to engage TB prevention and control services as one of the key activities in their health care delivery packages.

Partnering with PPM health care providers would limit misdiagnosis, improve cure rates and reduce risks of drug resistance. Formally engaging the large proportion of health care providers in tuberculosis prevention and control activities in an organized way could improve stagnant case notification, inappropriate tuberculosis case management and irrational use of tuberculosis medicines which possibly lead to spread of drug-resistant tuberculosis. Thus national tuberculosis control program needs to scale up country-specific public–private mix DOTS (PPM-DOTS) approaches which are already working well in many countries.

1.2 The benefits of PPM in TB care and control

1.2.1 Quality care for all patients: PPM helps healthcare providers to practice evidence based TB prevention and control. It gives them an opportunity to follow national and international standards for quality of care. They will improve the service continually.

1.2.2 Early and increased case detection: PPM helps increase TB case detection (by 10.0-60.0%) and reduces diagnostic delays by involving all health care providers in timely referral and diagnosis of TB.

1.2.3 Improved Adherence to standard: PPM has shown significant uptake of national guidelines, protocols, patient registration tools and reporting mechanisms. Similarly it also improved rational use of anti-TB drugs as per regulatory requirement.

1.2.4 Improved equity and access: PPM improves access to treatment by involving health care providers from whom the poor, marginalized and most vulnerable seek care.

1.2.5 Reduced financial burden and improved convenience: PPM reduces costs to patients by ensuring that TB medicines are free of charge and all other costs are kept to a minimum. PPM can also reduce indirect costs for patients by providing services closer to their homes or workplace. PPM creates an opportunity for patents to get convenience by availing the service based on their preference and comfort.

1.2.6 Improved partnership among health care providers: PPM contributes for improved referral and communication networking among health care providers in public and private sectors.

1.2.7 Better surveillance: PPM contributes to better TB and TB/HIV surveillance when all health care providers who keep TB and TB/HIV recording and reporting routines linked to national information systems. It allows surveillance of TB cases among all patients, PLHIV and HIV surveillance among TB patients.

1.2.8 Improved management capacity: PPM improves the management capacity of both the public and the private sectors and can contribute to health systems strengthening in general

1.3 Objectives and intended users of the revised PPM-DOTS Implementation Guideline

The current national policy promotes private health sector providers and other public health facilities to be engaged in TB prevention and control activities, according to the standardized methodologies and procedures included in this implementation Guideline.

The PPM-DOTS Implementation Guideline is designed to guide and support the effort made in engagement of PPM health care providers in wider scope of TB prevention and control activities. It will also inform the implementation of quality TB diagnostic services, PMDT interventions and TB/HIV care within the PPM model.

Different stakeholders involved in the coordination, management, implementation and monitoring of PPM DOTS initiative shall use this guide. This include policy makers, program managers and implementers, professional associations, academic communities, research institutes, health care providers, private sector business owners, and development partners who are interested in incorporating high-quality TB-DOTS service delivery through a private sector partnership with the national standards.

2. ENGAGING PPM HEALTH CARE FACILITIES IN TB, DR-TB AND TB/HIV CONTROL

Health care facilities have potential to deliver health care for customers who demand their services. These health care facilities are diverse in type, level in health tire system and nature of the health services being offered. Administratively, PPM health care facilities are not directly linked with the main NTP structure. Figure 1 depicted the relationship and types of health care providers under national tuberculosis prevention and control in Ethiopia.

An organized mix of TB care providers

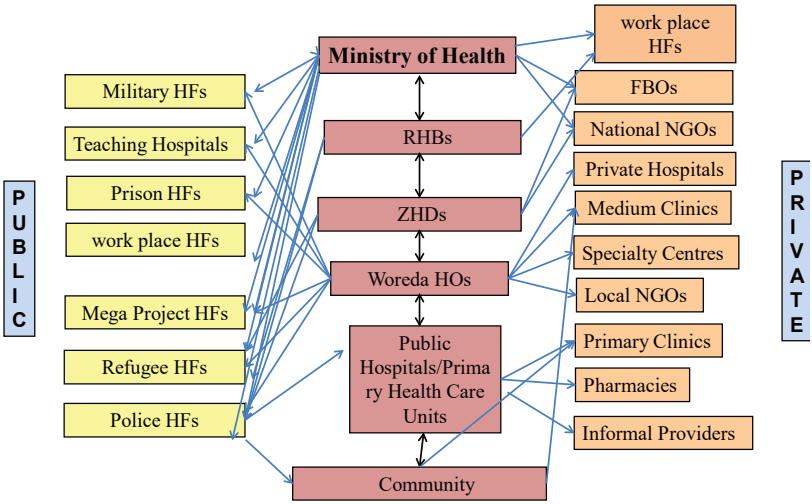

Figure 1: Types and Relationships of Health Care Providers

2.1 National policy support for PPM Engagement

In Ethiopia, there are enabling policy environments and programs to promote public private collaboration. Since 1997, national health policy has been promoting the participation of private health sector and non-governmental organizations in health care delivery. National drug policy, investment policy, PASDEP, GTP, Health Care Financing Proclamation and several other operational documents are also supporting the partnership with private and other public sectors in health services delivery.

FMOH has also initiated and coordinated the development of strategic framework for PPPH. The current national health policy has also emphasized on the need to widely promote inter-sectoral collaboration and the engagement of the private and other public health sectors to address unprecedented gaps in the delivery of health care in the country. PPM approach can play a crucial role in achieving the four HSTP transformation agendas; quality and equity in healthcare, information revolution, woreda transformation and developing caring, respectful and compassionate health professionals through providing additional opportunities for the public health sector to engage more health care providers outside main public health structure.

The health sector transformation plan has re-iterated the importance of collaborative endeavor of the the developmental partners and the private for profit health delivery system to achieve better health outcomes. The collective actions by all stakeholders outside the health sector including other public and work place health care providers would also play a critical role in improving the health status of the people.

2.2 Goals and objectives of PPM-DOTS in Ethiopia

2.2.1 The overall goal of PPM DOTS initiative is to contribute to the ending of TB epidemic in the country by the year 2035.

2.2.2 Specific objectives

- To improve equity and access for effective and affordable TB control and prevention services in order to enhance
    - o Early detection of both drug susceptible and drug resistant tuberculosis cases
    - o Quality of TB diagnosis including universal access to DST
    - o Patient treatment outcome
- To improve TB case findings
- To optimize the allocation and the use of resources in public and private health sectors for TB prevention and control
- To assure continuous quality improvement in TB and DR-TB care
- To play a catalytic role for TB/HIV collaborative activities

- To strengthen referral linkage and communication among public and private health care providers.

2.3 Principles and values of public-private partnership in Ethiopia

Engaging all relevant health care providers in TB care and control through public-private mix approach is an essential component of the WHO's End TB Strategy. PPM for TB care and control represents a comprehensive approach for a systematic involvement of all relevant health care providers in TB control to promote the ISTC and achieve national and global TB control targets.

According to the WHO guideline, public-private partnership (PPP) is about combining different skills and expertise in a framework of defined responsibilities, roles, accountability and transparency to attain a common goal of achieving universal access to the best quality health care that may be unattainable by independent action.
The Principles of PPP include:

- Securing trust between public and private partners
- Establishing parity of relationship among public and private sector partners
- Nurturing public-private partnerships
- Sustaining collaboration among partners
- Being equitable and inclusive
- Creating enabling policy environment for PPP for health (PPP-H).
- Values of PPP include:
- Participation, accountability, transparency, consensus-building
- Leadership vision, capacity and ownership
- Community centered health planning and implementation
- Abiding by the code of professional ethics
- Remaining flexible and ready to accommodate new health developments

2.4 The PPM Care Model for Ethiopia

PPM-DOTS in Ethiopia has been implemented under a strong framework of the organization, coordination, and management at different levels of the healthcare structure using a TB care model that fits into the existing health service delivery system as it is seen in figure 2.

The earlier model is modified to clearly indicate the organization and placement of the specific PPM health care providers with the current guidance towards scale up the PPM-DOTS interventions throughout the country. The model is presented in alignment with main NTP structures at all levels, stakeholders, and PPM health care providers. The roles and responsibilities of different stakeholders in the model are specified below.

The model also presented potential private, other governmental and workplace health care facilities which are operating outside main NTP structure. The model also mentioned types of health facilities under each category as follow; private-for-profit health care facilities (private hospitals, clinics, centers, diagnostic labs and drug outlets); private-for-non-profit health care facilities (faith-based organization clinics and NGO clinics), other governmental health care facilities (defense, Police, universities, refugee, prisons health facilities and etc) and workplace healthcare facilities (mega projects and workplace clinics).

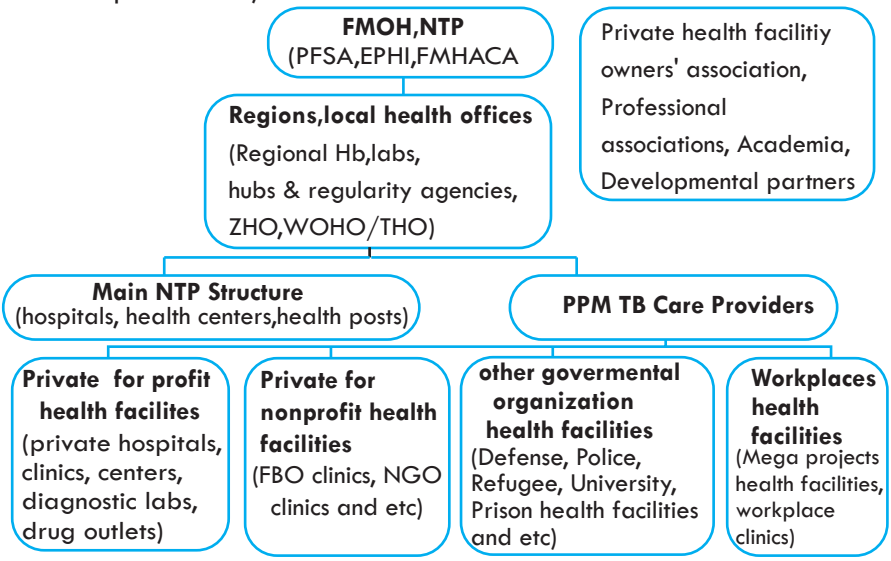

Figure 2: PPM Model for Ethiopia

2.5 Roles and responsibilities of stakeholders in PPM-DOTS

PPM-DOTS initiative implementation process requires the committed and rigorous contributions of various stakeholders within the national health system as shown in the care model. Identifying the role and responsibilities of each stakeholder assists the partnership to be effective at all levels and expedite the scale up of PPM DOTS implementation.

Each of the PPM-DOTS stakeholders shall play its role as indicated below:

2.5.1 FMOH

- Provides overall leadership, stewardship and oversight of the PPM initiative
- Formulates national policy and guidelines on engaging PPM health care providers in TB care and control
- Sets national targets and provide direction for the expansion of PPM-DOTS.
- Creates smooth communication and partnership with other governmental organizations, private health employers association, professional associations and PPM DOTS facilities
- Build the capacity of the regions and associations to effectively implement and manage PPM program
- Ensure allocation of adequate resource for implementation of PPM activities
- Lead and coordinate the national PPM technical working group
- Ensure recording and reporting of PPM program activities are well integrated in to the national HMIS system
- Monitor and evaluate the implementation of PPM initiative
- Provide ongoing technical support to the regions for strengthening implementation PPM activities
- Develop tailored training curriculum for PPM DOTS facilities engaged in different task - mix

2.5.2 Regulatory agencies (FMHACA)

- Formulate an enabling policy and regulatory environment for PPM health care facilities
- Regulate to assure that the PPM-DOTS sites are staffed, equipped and operational to deliver expected TB care results
- Ensure that TB care is delivered according to national standards
- Participate in site assessment, site selection and authorization of TB services for PPM sites
- Ensure that PPM sites comply with the procedure to be followed in case of service close out
- Collaborate with the ministry of health in the effort of engaging various types of health facilities in wider scope of PPM service

2.5.3 Pharmaceuticals Fund and Supplies Agency (PFSA)

- Ensure all the PPM DOTS sites are linked to the national pharmaceutical supply management system
- Forecast national TB pharmaceuticals and other supplies need based on the demand of health including PPM health care facilities
- Procure ,store and monitor inventory of TB pharmaceuticals including PPM health care facilities
- Receive reports and requests from PPM health care facilities and distribute Anti TB medicine, reagent and supplies.
- Coordinate national TB and leprosy logistics technical working group and make sure the PPM DOTS agenda inclusive
- Maintain regular pharmaceuticals supply for PPM health care facilities as per need
- Build the capacity of PPM health care facilities in area of Pharmaceutical supply management and rational pharmaceutical use through provision of technical support

2.5.4 Ethiopian Public Health Institute (EPHI), Regional reference Labs

- Provide laboratory trainings for laboratory professionals working in PPM health care providers
- Implement laboratory quality assurance procedures
- Ensures the functionality of the laboratory network ,sample referral and results delivery system
- Conducts Operational research

2.5.5 EQA Centers

- Provide timely feedback to PPM health care facilities
- Prepare and distribute AFB reagents to PPM health care facilities under the EQA center's catchment
- Ensure Quality Assurance system for the testing sites
- Compile and send reports to regional reference labs
- Monitor the stock status of the required supplies in all the PPM sites

2.5.6 Regional Health Bureaus (RHBs) and Zonal health departments

- Lead, support and monitor the implementation of PPM DOTS activities in their respective administrative areas
- Identify private and other governmental health facilities which are capable to deliver standard TB prevention and control services
- Assess, select and prepare PPM health care facilities for TB and TB/HIV services
- Sign MOU with PPM health care facilities to formally engage them in the provision of TB prevention and control service
- Involve the regulatory body at all level and other local stakeholders during assessment, selection and certification of PPM health care facilities
- Facilitate the distribution of TB reagents, TB drugs and other necessary supplies through the national supply system

- Provide relevant recording and reporting tools for PPM health care facilities
- Ensure all the PPM DOTS sites received specific HMIS code
- Distribute national PPM DOTS implementation guideline, national TB, TB/HIV guideline and other provider support tools and formats
- Provide appropriate trainings to the PPM health care providers
- Conduct regular supportive supervision, program monitoring and evaluation
- Timely collect, review, compile and submit PPM TB performance report to next level

2.5.7 Woreda/Town health offices

- Identify private and other governmental health facilities which are capable to deliver standard TB and TB/HIV services
- Participate in the assessment, selection and preparation of PPM health facilities for TB and TB/HIV services
- Identify training needs of PPM health facilities and communicate to the regional health bureau/ZHD
- Provide facilities with the relevant recording and reporting tools (HMIS recording and reporting tools, IPLS tools, and Laboratory tools) for proper recording and timely reporting of TB services
- Ensure timely delivery of TB commodities (Anti-TB drugs, reagents and other commodities) to PPM health facilities in coordination and collaboration with national Pharmaceutical supply chain system
- Ensure all PPM health care facilities received specific HMIS code
- Distribute national PPM DOTS implementation guideline, national TB, TB/HIV guideline and other provider support tools and formats
- Conduct quarterly supportive supervision and program monitoring by using national/regional standard tools

- Randomize slides from AFB microscopy sites and transport them to EQA center for blind rechecking
- Coordinate bi-annual on site supervision for EQA participating health facilities
- Collect feedback from EQA centers and communicate to PPM health facilities
- Timely collect, review, compile and submit PPM TB performance report to next level
- Participate PPM health facilities in TB prevention and control program review meeting
- Regularly supervise PPM health facilities logistic system
- Strengthen the referral linkage and communication system of public and private health care providers.
- Actively participate in lost follow up tracing of TB patients

2.5.8 Public health facilities

- Facilitate the referral and communication mechanisms between public and private providers
- Facilitate linkage of PPM-DOTS sites with their TB prevention and control services
- Provide TB/HIV services to TB patients referred from PPM health care facilities
- Support the PPM DOTS sites by providing TB drugs and reagents as appropriate
- Provide mentorship and guidance to PPM health care facilities that execute TB prevention and control service in their catchment area

2.5.9 PPM health care facilities

- Provide TB and TB/HIV services as per the national standard
- Proper recording and reporting of all program activities using national HMIS tools
- Ensure TB services are delivered by appropriately trained personnel
- Maintain a strong referral and communication network with all PPM health care facilities
- Collaborate and communicate with local health offices for PPM DOTS implementation
- Ensure use of rapid TB diagnostic tests such as Gene x-pert for eligible patients
- Implement minimum TB IC interventions at the facility level
- Report & request TB program supplies through IPLS

2.5.10 Professional and private health facilities employers' associations

- Advocate for public private partnership to support national TB control and prevention strategy
- Support the implementation processes with technical and operational support
- Collaborate with NTP in capacity building of health care providers on the national TB, TB/HIV diagnosis and management standards
- Collaborate with FMOH/RHBs in the assessment, selection and engagement of PPM TB sites
- Ensure the private health facilities provide quality TB diagnosis, referral and treatment services
- Contribute in the formulation and development of national policy and regulatory framework

2.5.11 Developmental partners

- Provide the necessary technical and financial support for effective implementation of PPM DOTS
- Collaborate with the regions in site assessment, selection and initiation of TB service in PPM DOTS sites
- Ensure delivery of quality TB, TB/HIV services in PPM sites as per the national standard
- Closely work with the local health offices and PPM DOTS sites to generate and disseminate evidences and best practices
- Assist regions in organizing capacity building trainings for PPM health care providers
- Plan and implement TB control activities in close collaboration with NTP

3. PROGRAM COORDINATION AND MANAGEMENT

3.1 Service areas for engaging PPM health care facilities in tuberculosis prevention and control Activities

Health care facilities operating outside the jurisdiction of FMoH/NTP are encouraged to be engaged in the delivery of the following TB prevention and control activities:

- Advocacy, communication and social mobilization
- Identification and referral of presumptive TB cases to nationally accredited diagnostic centers
- Participation in diagnostics and quality assurance services
- Treatment delivery services
- Community TB care services
- Mentoring, supportive supervision and monitoring of performance
- Provide TB/HIV services
- Sputum sample collection and transportation services to designated diagnostic centers

The delivery of one or any combination of services can be initiated by a PPM health care facility after fulfilling the requirements; completion of preparatory procedures and signing a memorandum of understanding with the appropriate governmental body, usually Regional Health Bureau.

3.2 Procedures for engaging PPM health care facilities in TB prevention and control activities

There are a series of activities that, when conducted step-by-step, create a roadmap for the successful implementation of a PPM-DOTS program. These are:

- Sensitization and consensus building Meetings
- Facility Assessment
- Site Selection
- Capacity Building
- Memorandum of Understanding (MOU)
- Service Initiation
- Referral Network
- Community Awareness and Service Promotion
- Logistics Management
- Laboratory Quality Assurance
- Monitoring and Evaluation

3.2.1 Sensitization and consensus building Meetings: This is an essential step in the implementation of PPM for TB prevention and control. It is a forum that is organized to engage RHB Officials, regulatory and supply overseeing authorities, ZHDs/Woreda/Town Health Office officials and intended health facilities in the initial planning process. The meeting should serve as a forum to thoroughly explain the approach, targets and timeline of implementation. The Sensitization Meeting is expected to help participants understand the concept of PPM initiative for TB prevention and control, the roles and responsibilities regarding who does the referral, treatment, provision of drugs, supplies as well as reporting requirements. It also serves as a platform to share experiences by participants. The forum enables the participants to know about the site selection criteria to assure transparency.

3.2.2 Facility Assessment: Using a standardized questionnaire, a team composed of RHB/ZHD, local health office (regulatory and TB experts) and partners conduct facility readiness assessment of potential health facilities including, resources available and the needs of the facility. The assessment should detail each facility's current infrastructure, human resources, training requirements for staff, laboratory facility and equipment, and willingness to participate in TB prevention and control activities.

3.2.3 Site Selection: It is important to clearly state the minimum requirements for engaging health facilities in each level of intervention areas of PPM for TB prevention and control. The minimum requirements for choosing potential PPM health care facilities in specific intervention areas are stated under section 3.3.

3.2.4 Capacity Building: To maintain the quality of service in program implementation, health care providers must be appropriately trained on the standard national guidelines. Training is necessary to encourage adherence to national protocols and guidelines and standardization in patient care.

3.2.5 Memorandum of Understanding: The MOU establishes a formal relationship between the RHB/ local health structure and the PPM health care facility. It should clearly articulate the roles and responsibilities of both the RHB/local health structure and PPM health care facility. MOU is mandatory for facilities that will be engaged in TB/DR-TB diagnosis and referral or TB/DR-TB diagnosis and treatment service. It can be customized depending on the type of PPM health care facilities.

3.2.6 Service Initiation: Once the facility signs MOU, the delivery of TB program supplies (TB drugs, reagents, consumables) and recording and reporting tools should be facilitated by woreda/town health office. Besides a team composed of local health office experts and partners will conduct service initiation visit and onsite coaching from the very inception of the program.

3.2.7 Referral Network: An effective referral network ensures continuity of care, is able to track patient's progress and patients get the care that they need. RHBs/local health offices should map, prepare and distribute the list of facilities providing TB prevention and care service to health facilities that are found in their catchment. Besides the RHB should network PPM health care

facilities to the nearby gene Xpert sites and facilitate specimen transportation and result delivery system. Full cooperation and coordination by the public and PPM health care facilities ease the referral and feedback mechanism,

3.2.8 Community Awareness and Service Promotion: Promotion of PPM services to create community awareness about available TB services in the PPM health care facilities is essential. Print materials like signage, billboard and electronic materials should be used to create demand for PPM health care facilities. The community should be aware that TB drugs are dispensed for free to the public.

3.2.9 Logistics supply Management: Logistics supply management is a critical part of TB prevention and control program. The NTP along with PFSA should arrange a mechanism for the delivery of an adequate and uninterrupted supply of drugs, reagents and other consumables to PPM health care facilities.

3.2.10 Laboratory quality Assurance: All PPM health care facilities engaged in TB diagnosis service should be linked to the nearby EQA center for TB Laboratory Quality Assurance. EQA centers should regularly assure the quality of TB diagnostic services of PPM health care facilities and provide timely feedback which will enable them to deliver accurate and reliable results. Moreover the health care facilities will be encouraged to conduct internal quality control on a regular basis.

3.2.11 Monitoring and Evaluation (M&E): A monitoring and evaluation system must be in place to ensure appropriate use of resources, to assure the quality of services rendered and to generate data for decision-making. Monitoring and evaluation will help to evaluate the outcomes of the program implementation while measuring both short and long term impact. Partners, regional authorities and facility staffs need to facilitate and undertake program monitoring through supportive supervision and by organizing program review meetings with all stakeholders. M&E frameworks also facilitate the timely submission of reports to appropriate health offices and documentation of promising practices which assist dissemination of program successes.

3.3 Minimum requirements for engaging health care facilities in TB prevention and control service provision

The minimum requirements for engaging health care facility operating outside the jurisdiction of FMoH/NTP in the provision of TB prevention and control services depend on the level of service it is expected to provide.

3.3.1 Health care facilities to be engaged in TB diagnostic and treat ment service

These facilities are expected to provide TB diagnosis and treatment services and refer patients for any other needed care to other facilities. Health care facilities agreeing to provide diagnostic and treatment services should fulfill the following requirements:

- Facility willingness to participate in PPM TB prevention and control services
- Renewed license for the current physical year
- Designated room for DOTS (It could be separate or integrated with other programs/activities)
- Water supply inside the lab room
- Microscope with 100X magnifying field
- Basic Infection prevention equipment and supplies
- Human resources:
  - ✓A minimum of one MD / health officer/BSC nurse
  - ✓ Health worker assigned for DOTS service
  - ✓A minimum of two nurses
  - ✓A minimum of one laboratory technician
- Availability of general medical and basic laboratory services

3.3.2 Health care facilities to be engaged in TB diagnostic and referral service

These types of facilities did not have adequate infrastructure and human resource for the provision of TB treatment service but they are capable to provide TB diagnosis and referral service. PPM health care facilities to be engaged in TB diagnosis and referral service must fulfill the following criteria

- Facility willingness to participate in PPM TB prevention and control services
- Renewed license for the current physical year
- Water supply inside the lab room
- Microscope with 100X magnifying field
- Basic Infection prevention equipment and supplies
- Human resources:
    - ✓ A minimum of one MD / health officer/BSC nurse
    - ✓ A minimum of two nurses
    - ✓ A minimum of one laboratory technician
- Availability of general medical and basic laboratory services

3.3.3 Health care facilities to be engaged in providing presumptive TB case identification, referral and TB treatment/DOT/ service

These types of health facilities usually do not have the infrastructure or human capacity for diagnostic services but they are potential service providers in terms presumptive TB case identification and referral service and also in the provision of directly observed treatment

- Facility willingness to participate in PPM TB prevention and control services
- Renewed license for the current physical year
- Dedicated room for DOTS -It could be separate or integrated with other programs/activities)
- Health worker assigned for DOT service
- General medical services

3.3.4 Health facilities to be engaged in presumed TB case identification and referral service

These health facilities usually do not have the human or infrastructure to diagnose or treat TB cases (e.g. primary clinics, drug outlets). These health facilities will identify and refer presumptive TB cases to facilities that can provide both services at a location convenient for the patient.

3.3.5 Requirements for engaging PPM health care facilities on MDRTB services

Implementation of the MDR-TB program requires prior assessment of the status of the health facility on programmatic requirements and status of infection control measures. The PPM health care facilities can be engaged as TIC and TFC based on the criteria listed under the national PMDT guideline.

Table1: PPM task mix for different level of care providers

Tasks	Primary clinics/HP	Medium clinics	Specialty Clinics	Health center	Specialty Centres	Hospitals (primary, general, specialized)	Pharmacies (drug shops, pharmacies)	Labs (basic, advanced labs)
Identify presumptive TB cases	+	+	+	+	+	+	+	-
presumptive TB cases referral	+	+	+	+	+	+	+	-
Sputum collection	+/	+	+	+	+	+	-	+/-
TB diagnosis using Bacteriologic methods	-	+	+	+	+	+	-	+
TB diagnosis using supportive evidences	-	+/-	+	+/-	+	+	-	-
Provide treatment services	-	+	+	+	+	+	-	-
Inform patients about TB and TB treatment	+/-	+	+	+	+	+	-	-
Decide to Initiate TB treatment regimen	-	+	+	+	+	+	-	-
Identify DOT provider/supporter	+/-	+	+	+	+	+	-	-
Supervise DOT	+/-	+	+	+	+	+	-	-
Follow up with treatment	-	+	+	+	+	+	-	-

Tasks	Primary clinics/HP	Medium clinics	Specialty Clinics	Health center	Specialty Centres	Hospitals (primary, general, specialized)	Pharmacies (drug shops, pharmacies)	Labs (basic, advanced labs)
DR-TB risk assessment and referral for DST screening	-	+	+	+	+	+	-	-
Contact tracing and management	+/-	+	+	+	+	+	-	-
TB/HIV screening and diagnosis and linkage	+/-	+	+	+	+	+	-	-
Adverse event management	+/-	+	+	+	+	+	-	-
Retrieval of interrupters	+/-	+	+	+	+	+	-	-
Recording on UNIT TB register	+/-	+	+	+	+	+	-	-
Reporting activity performance	+	+	+	+	+	+	+	+
ACSM	+	+	+	+	+	+	+	+

[1]ARA have health posts that are responsible for presumptive case identification and DOT service

3.4 Training

The success of PPM initiatives depends on how well health care providers are sensitized and trained. Service providers in PPM health care facilities should be trained on presumptive TB case identification, TB diagnosis and management. NTP training materials and methods should be used as a basis for developing specific tailored training materials for the different groups.

The training type depends on the level of engagement by the facilities. Moreover, training materials and methods need to be suitably adapted to special needs and working conditions of different types of providers.

3.5 Service charges

It is important that the cost of reagents and TB drugs are not passed on to patients seeking TB diagnosis and treatment in the PPM health care facilities so that the services may be accessed by the majority of TB patients regardless of income level. This enables improved equity of health care services in

PPM health care facilities. However, to ensure continuity of service and provider's commitment to the program, the private health facilities may need a reasonable service fee to cover indirect costs in making TB and TB/HIV services available for users. There should be clearly presented statements that describe all service related fees.

Each region negotiates the cost of TB services through joint action of PPM health care facilities and the RHBs/local health authorities as stipulated in locally signed MOU/service agreements.

3.5.1 Service areas whereby no charges should be incurred: The NTP is expected to procure all necessary commodities for the PPM-DOT health care provider and the patient will receive the following service free of charge:

- AFB microscopy Laboratory services: Direct smear microscopy tests for AFB including Quality Assurance service to AFB lab service. Regional/-sub-regional laboratories and EQA centers are responsible for preparing and providing AFB reagents to the PPM-DOTS diagnostic centers. The centers will be supplied with all the necessary commodities required for AFB: slide box, microscope slide, sputum cup, wooden applicators, sharps-resistant safety box and biohazard bags. However private health facilities may incur reasonable indirect costs for manpower and other consumables like gloves.

- Sample transportation service for diagnosis of TB/DR-TB: As part of national TB/DR-TB case finding sample transportation services to the designated diagnostic sites will be provided at no cost.

- Gene Xpert test: Xpert test should be done for free for all eligible clients in health facilities with Xpert machine supplied by government or developmental partners. Xpert sites will be supplied with the necessary commodities for Xpert test and will also participate in quality assurance scheme. However reasonable service fee should be paid to cover the indirect costs of human resource and consumables.

- Culture and DST diagnostic services: culture and DSTs performed to diagnose MDR-TB cases as per the national guidelines should be delivered free of charge as long as the service is provided in governmental diagnostic centers.

- Treatment services: Clinic visits made by TB patients for routine direct observations of treatment (DOT) practice and regularly scheduled follow-up visits are free of charge.

- Pharmaceuticals and dispensary services: All TB drugs are procured by the national program; no cost will be incurred for procuring and dispensing these drugs through a PPM health care facility.

3.5.2 Services areas where patients may be charged according to the facility's standard fee schedule

- TB diagnostic tests other than xpert and direct sputum smear microscopy examination

- Investigations for smear negative and extra pulmonary TB cases, imaging techniques, histopathology tests, serologic and organ function tests

- Ancillary medicines prescribed for TB patients, as long as it is not procured by the program

- Medical consultations outside the TB clinic or for inpatient services

3.6 Patient referral services

- A patient is said to be referred when he/she is sent to another health facility for better diagnosis, consultation and management and/or other programmatic reasons. A patient with symptoms suggestive of TB disease may be sent to other health care facilities for TB diagnosis or who is diagnosed to have TB in one health facility might be referred to another health facility for starting or continuing anti-TB treatment.

- To strengthen the referral and feedback system between facilities providing TB prevention and control service RHBs and town health offices should map, prepare and communicate the list of facilities providing TB service to all health facilities located in the catchment. When a medical referral or transfer is needed, the referring facility should complete the Referral form and send it with the patient, addressed to the appropriate health institution and the receiving facility should send the feedback to the referring facility.

3.7 Certification and de-certification

Certification is the process by which the NTP officially documents that a PPM facility of any size has met the appropriate criteria to provide the services requiring certification. The certification also would require compliance with a uniform set of national standards and procedures essential for proper delivery of standardized, quality TB care. Certified facilities may be de-certified for PPM, following repeated warnings, for providing poor-quality. Causes for de-certification include unnecessary financial exploitation of TB and TB/HIV patients such as selling TB drugs. De-certification involves revocation of the MOU in place, stopping distribution of drug supplies, announcement of facility de-certification, and potentially taking legal actions as deemed necessary.

Prior to the cessation of drug supplies, appropriate arrangements must be made so that those patients on treatment and follow-up are transferred to a nearby certified health facility or are allowed to finish their treatment in order to avoid inconveniences and extra expenses that may result in interruption of treatment.

3.8 PPM quality assurance mechanism

a. Access to quality assured sputum smear microscopy services is one of the key elements of the DOTS strategy:

- PPM facility laboratories perform all duties of AFB microscopy as indicated in the laboratory manual including internal and external quality control system.

- PPM facility laboratories will follow national standards and participate in external quality assurance. (Refer to AFB manual)

b. Standardized reporting and recording system for monitoring of TB and TB/HIV patients will be implemented, as per the NTP guidelines.

c. Ensure timely delivery and adequate supplies of drugs and other consum ables to the private health facilities

d. Basic indicators to monitor the national TB and TB/HIV activities (refer to updated TB, Leprosy and TB/HIV program manual)

e. Training of staff and supervision will also be regularly conducted by the NTP in the private sector to assure the quality and standardization of services provided.

f. Improve health care services by conducting operational research activities in PPM health care facilities.

3.9 Incentives

Incentives are usually most effective when they are not financial. Apart from serving the society, public-private partnerships tend to retain clients and garner recognition from the health system and national program. Distribution of drugs and reagents by the national program free of charge is the one of indirect incentives. The program also offers training, supportive supervision, EQA of microscopy services, and other general support to PPM health care facilities for better case management as well as enhanced patient satisfaction and confidence in the health care providers. This is of great importance for the perceived benefits of PPM-DOTS to private health providers as consumer satisfaction is of key significance and determines future health-seeking behavior.

3.10 Procedure for service close-out

PPM health care facilities should follow service closure procedures whenever they decide to end TB service provision.

a) The PPM health care facility should communicate with the responsible local health office its plan to close-out the service with a written application at least three months prior to the planned close-out date.

b) All patients on treatment and follow-up in the clinic should be transferred to nearby health care facilities; managers of the facility should allow a grace period of 2-4 weeks to allow for a smooth and complete transfer-out of patients on treatment and follow-up.

c) The facility must prepare and submit a complete patient status and locator report to the nearest health office.

d) The health office should confirm that all transferred patients are enrolled in the accepting facilities.

e) The clinic must return all unused and unconsumed supplies (TB drugs, reagents, registers and other M&E tools) to the respective health offices.

f) The respective health offices dissolve the MOU and issue a testimonial letter for legal termination of the service.

If the PPM health care facility is to be closed for reasons of legal issues or regulatory concerns, the regulatory body must give a transition period for the clinic to take necessary steps for safe and complete closure of services.

4. TUBERCULOSIS PATIENT CARE IN PPM-DOTS PROGRAM

PPM-DOTS health care facilities should generally comply with the national and international standards of TB diagnosis, treatment and prevention of TB disease transmission and progression.

4.1 General definitions

4.1.1 Presumed Tuberculosis Case: Any person who presents with symptoms and/or signs suggestive of TB, in particular cough of two weeks or any duration for HIV positive client

4.1.2 A proven case of tuberculosis: A patient with one sputum-positive smear or culture positive for Mycobacterium TB; also a patient with Mycobacterium TB complex identified from a clinical specimen, either by culture or by a newer method such as molecular line probe assay and Gene Xpert

4.1.3 Clinically diagnosed TB case: A clinically diagnosed TB case is a patient who does not fulfill the criteria for a bacteriologically confirmed case, but has been diagnosed with active TB by an experienced clinician and is decided to be given a full course of TB treatment. This definition includes cases diagnosed on the basis of X-ray abnormalities or suggestive histology and extra-pulmonary cases diagnosed without confirmation of Mycobacterium TB

4.2 Standards of TB diagnosis

All PPM DOTS health care facilities should make the diagnosis of tuberculosis based on the national TB diagnostic approach. The policy recommendations on the national algorithm for TB diagnosis, drug susceptibility testing and patient management states that:

- All presumptive pulmonary TB cases should submit sputum for bacteriologic examination with Xpert MTB/RIF assay or sputum microscopy.

- If Xpert service is accessible on the same day, Xpert MTB/RIF test is recommended as the initial diagnostic test for all persons with presumptive TB.

- If Xpert service is not readily available on the same day, sputum microscopy should be used as the primary diagnostic test for tuberculosis in the interim to avoid diagnostic delay. In the meantime, a sputum specimen should be sent for Xpert testing for Eligible population group including HIV positives, children, and previously treated or other DR-TB risk group patients to detect additional cases of TB and/or screen for possible RR-TB.

- All individual diagnosed with TB should undergo drug resistance screening test at least for rifampicin at baseline using a rapid DST technique preferably by Xpert or FL-LPA.

- Patients with unexplained finding on CXR should submit sputum for confirmatory test preferably by X-pert MTB/RIF test.

- For all patients with confirmed RR/MDRTB, send sputum for SL-DST using LPA for core Second line drugs before or within one week of treatment initiation with DRTB regimen.

- DR-TB Patients with reported resistance on SL-LPA, are to be confirmed using culture and phenotypic DST while the patient is managed on the basis of Xpert/LPA result.

- In patients in whom the diagnosis of TB remains in doubt despite negative results on AFB and/or Xpert tests; additional investigations may be performed as needed.

- Individuals with presumptive or confirmed TB should be offered a rapid HIV test.

4.3 TB case classifications and standard TB case definitions

Classification and cases definition of TB patients should be performed and documented in the Unit TB register as per the Guidelines for Programmatic and Clinical Management of TB, Leprosy and TB/HIV.

4.4 Selection of treatment regimen

Depending on the drug susceptibility of the Mycobacterium, the TB patients should receive appropriate TB treatment regimen (Standard first line treatment or MDR-TB regimen) according to the national guideline. The PPM DOTS health care providers should be well aware that re-treatment regimen for eight months with the addition of streptomycin should no longer be prescribed for patients coming to receive treatment for a repeated TB episode.

4.5 TB patient preparation to start treatment

The success of TB treatment outcomes depends on the patient's cooperation and continued motivation. Adequate patient preparation and continued support are essential for optimal treatment outcome. Good patient preparation begins with the provision of all the essential information on TB to the patient at diagnosis. Health workers at the PPM-DOTS sites should therefore give TB patients all the necessary information about their treatment so that they understand the disease and the need to adhere to the treatment regimen.

4.6 Provision of DOTS and follow up services

The PPM DOTS health care facilities should provide DOTS service to TB patients as per the national guideline. Health workers must take an active role to ensure that every patient takes the recommended drugs, in the right combinations, on the correct schedule, and for the correct duration. TB patient treatment supporters including health extension workers can be engaged in enhancing the adherence of TB patients along with the TB focal persons.

During the course of treatment, the PPM DOTS health facilities should properly monitor TB patients for progressive clinical response, perform scheduled follow up AFB smear examination, identify and manage side-effects as early as possible, and provide continuous adherence support. Details of the patient's progress monitoring standards are available in the Guidelines for Programmatic and Clinical Management of TB, Leprosy and TB/HIV and must be followed completely.

4. 7 Tracing of treatment interrupters and lost to follow up

If, during TB treatment, a patient has not attended on the appointed clinic day for DOT and fails to report in for the next two days thereafter (thereby interrupting treatment), he or she has to be considered a treatment interrupter and should be located and returned to treatment as quickly as possible. The PPM DOTS health care provider should immediately communicate the patient, if possible, or notify the contact person recorded in the Unit TB register, and request his/her assistance to encourage the patient to return for treatment. If this fails, the local health offices and primary health care units should be communicated for the necessary support in tracing the patient. All available means need to be put into action when a patient misses a scheduled visit, but the methods of tracing patients differ from one center to the next: it can be done by telephone, home visits, or even visits by a neighbor being treated at the same center.

Lost to follow up patients are those patients who have been started ant-TB-treatment and discontinued treatment for more than eight consecutive weeks. Whenever the patient is found to be lost to follow up, the tracing activity requires a concerted effort by the health care providers, the HEWs, the patient's contact persons and family members as well as members of the community.

Roles and responsibilities of the PPM-DOTS health care facilities, the public health sector and the community in tracing treatment interrupter are outlined as follows:

4.7.1 PPM-DOTS health care facility

- Make every effort to locate the patient through the measures and means described above for tracing absentees.

- Notify the respective woreda/town administration health office using a standard notification letter for tracing treatment interrupters and document this action

- Follow up with the woreda health office TB officers for status of dropout patients

4.7.2 Woreda/town health offices

- Notify the health center in the woreda/town to communicate with the HEWs from the patient's village about the dropout patient
- Notify the HEWs directly whenever possible
- Follow the status of the missing patient and provide feedback to the PPM-DOTS health care facility

4.7.3 Health center in the woreda or town

- Notify the HEWs directly responsible for the patient's village to trace the dropout
- Communicate with the patient's contact whenever possible
- Follow up on the status of the missing patient on a regular basis with the HEWs and provide timely feedback to the PPM-DOTS site

4.7.4 Health extension workers

- Locate and contact the missing patient and refer him/her back to the PPM DOT sites.

4.7.5 The community

- Encourage and support the patient to adhere to treatment
- Notify the HEWs responsible for the kebele when they locate a missing TB patient

N.B: Subsequent management of TB treatment interrupters and lost to follow up cases should be made as per the National Guidelines for Clinical and Programmatic Management of Tuberculosis, Leprosy and TB/HIV.

4.8 Strategy to minimize transfer-out rate

Transfer-out is one of the major causes of an unfavorable treatment outcome, not evaluated, since it is difficult to ascertain the final status of such patients. The best strategy to avoid transfer out is to initiate TB treatment at a DOTS clinic located close to the permanent residence of the patient. Before putting patients on TB treatment, the PPM DOT health care provider needs to identify

the nearest DOTS center (private or public) jointly with the patient to decide where to start treatment in the private facility or to refer the patient to the nearest DOTS center closer to a patient's residence. In certain circumstances, the PPM DOTS health care facilities may start treatment for their patients for few days, but such patients should not be registered in the unit TB register unless they took treatment for more than a month in the same facility. When transfer out is inevitable, complete information with feedback should be communicated to the receiving health facility.

4.9 Steps to transfer TB patients to another health care facility

Patients may request to receive TB treatment at another health facility after starting at PPM-DOTS sites. In transferring the patient, all the necessary information should be documented in the patient transfer form, and communicate the referral receiving health care facility and the respective local health office to ensure the patients reached their destination to continue treatment. If the patient prefers to continue treatment at the health post level, the transfer should be made through the respective primary health care unit. Other means of referral/transfer within the context of the PPM DOTS health care facilities can also be explored to expedite the transfer process as much as possible.

4.10 TB/HIV collaborative activities in PPM-DOTS

Collaborative TB/HIV activities are essential to ensure that HIV-positive TB patients are identified and treated appropriately; and to prevent, diagnose and treat TB in people living with HIV (PLHIV). The PPM DOTS health care facilities should strictly adhere to the national guideline in implementation of the TB/HIV interventions. Accordingly, the facilities need to ensure that TB patients are tested for HIV and results are documented, TB/HIV co-infected patients are linked to chronic HIV care and treatment service and the patients are started or continued on anti-retroviral therapy and co-trimoxazole preventive therapy as per the national standard.

5. PROGRAM MANAGEMENT OF DRUG RESISTANT TB (PMDT) SERVICE IN PPM-DOTS

In the absence of any formal links with NTPs, the quality of diagnosis and management of MDR-TB by these providers remain questionable. Overall, there are reasons to believe that mismanaged TB patients unknown to NTPs

could be an important source for the emergence and spread of M/XDR-TB. A partnership between government and the outside main NTP sector could thus be used for making the best use of existing resources, to achieve scale up, while maintaining quality and positive outcomes. As part of the expansion of programmatic management of drug-resistant TB services, the national program encourages PPM DOT sites to get involved in one or more of MDR-TB components after fulfilling the preconditions set in the national PMDT and signing an MOU with the RHB.

5.1 Areas for involvement

5.1.1 Case finding: According to the national policy all previously treated and new cases with proven contact with confirmed MDR-TB cases or high risk groups must access DST service. Hence, All PPM DOTs sites must be involved in identifying presumptive MDR TB cases and facilitating access to DST service from the national program or an accredited private laboratory.

5.1.2 Access to DST service: MDR-TB case: PPM DOT health care provider should diagnose MDR TB cases and do DST if available or send specimen to designated diagnostic center.

5.1.3 Provision of DR TB cases treatment service (initiation and follow up): PPM DOTS health care facilities can possibly be engaged in the delivery of MDR-TB treatment service whenever the minimum standards are fully met as per the national PMDT guideline.

5.1.4 Implement community awareness initiatives: PPM DOT health care providers should play critical role in awareness-creation and community-mobilization activities related to MDR-TB prevention, treatment and adherence support.

6. PHARMACEUTICALS SUPPLY MANAGEMENT SYSTEM

In order to achieve sustainable PPM DOTS program implementation, it is essential to ensure that every health care facility involved in TB and TB/HIV control activities has an adequate and uninterrupted supply of drugs, laboratory reagents, medical supplies and equipment with assured safety, quality and efficacy.

6.1 Integrated Pharmaceuticals Logistics System and PPM health care facilities

According to Integrated Pharmaceuticals Logistics System (IPLS), Pharmaceutical Fund and Supply Agency (PFSA) will supply TB and TB/HIV pharmaceuticals directly to ART sites and through Who to indirect health facilities. PFSA is scaling up the system in the public health systems, and ultimately all PPM health facilities which are eligible to provide TB/ART sites services will receive the pharmaceuticals directly from PFSA whereas non-ART PPM health care facilities will receive the pharmaceuticals from nearby health center. PPM health care facilities providing only TB service for a significantly large population like other government and work place health care facilities should get the product directly from PFSA hubs.

Delivery and collection of pharmaceuticals scheduled every two months for TB/ART health care facilities directly from PFSA and every month for non-ART PPM sites from nearby health center. TB/ART health facilities can have a maximum of four months' stock and a minimum of two months' stock at any given time. Non-ART PPM health care facilities will have a maximum of two months of stock and a minimum of one month of stock. The list of pharmaceuticals that PPM health facilities get from PFSA is limited to those listed in the Guidelines for Programmatic and Clinical Management of Tuberculosis, Leprosy and TB/HIV.

6.2 Drug consumption recording, reporting and requisition forms

PPM health care facilities are required to use and routinely update the formats to monitor and report pharmaceuticals consumption. These formats include:

6.2.1 Bin card

Each TB/ART PPM health facility is required to regularly register all pharmaceuticals received from PFSA and issued from the health facility store to TB clinic to dispense to clients and be used for diagnostic purposes at the laboratory.

Each non-ART PPM health facility is required to regularly register all pharmaceuticals received from nearby health center and dispensed to clients and be used for diagnostic purposes at the laboratory.

6.2.2 Unit TB register

This register contains all the necessary patient-related information, and the type and quantity of drugs taken by the patients. It is updated whenever a patient consumes a dose of drugs. The data should be aggregated on a monthly basis and can be used to quantify the future needs of the facilities.

6.2.3 Report and Requisition Form and Private Clinic Monthly Report and Resupply Form

At the end of their reporting period, all TB/ART PPM-DOTS health facilities i.e., every two months, are required to fill and submit the Report and Requisition Form (RRF) to PFSA hub and respective Woreda health offices. All non-ART health facilities are required to fill and submit Private Clinics Monthly Report and Resupply Form (PCMRRF) to health center and respective Woreda health offices.

6.3 Roles and responsibilities on PSM

6.3.1 PPM health care facilities

- Keep desirable stock of pharmaceuticals at all times
- Keep up-to-date records on stock on hand, consumption, loss/adjustments, etc.
- Apply good storage guideline as per IPLS SOP and maintain the safety, quality and efficacy of all pharmaceuticals
- All TB/ART health care facility should fill and submit RRF timely to PFSA hub as per the reporting period and send a copy of the RRF to the responsible health office with which the MOU was signed or its delegate.
- PPM health care facilities which do not provide ART service but provide a significantly a big volume of service should fill and submit RRF timely to PFSA hub as per the reporting period and send a copy of the RRF to the responsible health office with which the MOU was signed or its delegate.

- All non-ART health care facility fill and submit PCMRRF timely to nearby health center as per the reporting period and send a copy of the PCMRRF to the responsible health office with which the MOU was signed or its delegate.

- All TB/ART health facility should get the laboratory reagents from respective regional labs or EQA center

- All non-ART health facility should get the laboratory reagents from nearby health center/ woreda health office/EQA center

- List the types and quantities of items that have expired, and notify the responsible body timely for disposal as per the directive.

- Ensure the rational use of drugs including rational diagnosis, prescribing, DOT and proper counseling.

- Dispense the drugs and use the reagents and supplies for diagnosing free of any charge to patients

- During supervisory visits, open facilities and make all documentation available

6.3.2 FMOH and PFSA

- Trainings on IPLS and other PSM-related trainings as well as technical assistance to staff at private health facilities

- The necessary pharmaceuticals and reporting and registration formats should be availed by FMOH and PFSA

- Conduct regular supportive supervision and give constructive feedbacks on the usage of pharmaceuticals at PPM health care facilities

6.3.3 Woreda Health Office, Sub-city Health Office and Zonal Health Department

- Supervise stock management, ordering, and reporting functions of health posts and health centers

- Compile and aggregate heath centers RRF and submit to PFSA hubs
- Check the quality (completeness, accuracy and timeliness) of RRF and PCMRRF, and provide feedback to PPM heath care facilities
- Make sure the pharmaceuticals are being used for the intended purpose
- Monitor the supply chain system performance (reporting rates, consumption rates, stock levels, storage conditions)

7. TB LABORATORY SUPPORT FOR PPM DOTS HEALTH CARE FACILITIES

The PPM DOTS health care facilities are required to provide TB laboratory diagnostic services based on the national standards. Accordingly, adequate technical and logistics support should be arranged to ensure and maintain the delivery of quality service.

7.1 Capacity Building

Laboratory professionals working at PPM DOT health care facilities should receive a standardized training on TB microscopy, Gene Xpert, and collection and transport of tuberculosis specimens as appropriate depending on the type of TB laboratory services provided in the facility. Besides, to further strengthen the quality of laboratory service regular supportive supervision and mentoring will be provided for PPM sites on regular basis by respective EQA centers & regional labs.

7.1.1 TB Laboratory Supplies & consumables

The PPM DOTS health facilities should obtain the necessary laboratory materials and consumables to provide TB diagnostic services continuously. Different types of TB laboratory diagnostic services can be delivered depending on the capacity of the facilities, thus the regional reference laboratories and regional health bureaus will seriously consider PPM health care facilities with a high patient load in the distribution and placement of new rapid TB diagnostic tools such as LED Fluorescent microscope and Gene x-pert machine.

7.1.2 Laboratory supplies and consumables

Regional health bureau and woreda health office should ensure PPM sites are linked with the supply system for laboratory reagents and other laboratory consumables such as falcon tubes, cartridges etc. which are necessary for TB microscopy service, Gene x-pert test and transportation of specimen for DST tests. If the PPM DOTS health facilities have the required capacity, they may prepare ZN & FM stains for themselves & distribute to their catchment facilities in consultation with the regional reference laboratory and local health offices.

7.1.3 Specimen Referral Arrangement

Universal access to DST service has been the core component in the effort to ensure early diagnosis of DS-and DR-TB. Since Gene x-pert service has not been readily available in PPM DOTS health care facilities, every effort should be made to ensure the health care facilities are properly linked with national specimen referral arrangements for Gene Xpert testing, and culture and DST services.

7.1.4 External Quality Assurance (EQA)

In line with the national EQA scheme, PPM DOT sites providing TB smear microscopy service should be linked with the nearby EQA centers for regular participation of REQAS through blinded rechecking and onsite evaluation. According to the national QA guideline all the PPM DOTS health care facilities should participate in blind rechecking on quarterly basis and on-site evaluation biannually. EQA feedback should also be communicated timely to the respective facilities so that appropriate corrective actions will be taken. PPM sites that are engaged in Gene expert test should also be monitored through national external quality assessment approaches.

7.2 TB Laboratory service in PPM DOTS health care facilities

7.2.1 AFB Microscopy Service

All the PPM DOTS health care facilities should implement Spot – Spot strategy for AFB smear microscopy. Appropriate standard operating procedures for sputum collection, smearing, staining and slide reading, should be strictly applied.

7.2.2 Gene x-pert service

PPM DOTS health care facilities with Gene x-pert machine should provide quality diagnostic service as per the national standard. All the implementation of Gene x-pert service should be aligned with the national guideline.

7.2.3 Specimen referral service

If Gene x-pert service is not available in the facility, specimen sample referral should be performed according to the national recommendation. PPM sites should collect one "on-the-spot" sputum samples & properly pack using triple packaging. The PPM DOTS health care facilities should follow the necessary precautions as per the Standard Operating Procedure (SOP) for Collection, Handling, Packaging and Transportation of Sputum Samples for TB Culture and Molecular Diagnostics. There will be a specimen transport log sheet at each facility on which the necessary information should be captured whenever the post office receives samples from the facility.

7.2.4 Quality assurance activities

TB diagnostic laboratories are required to have and implement a quality assurance arrangement with in its diagnostic system. The PPM DOTS health care facilities should regularly perform internal quality control for the specific TB smear microscopy areas as per the national SOP in the annex.

8. REGULATORY STANDARDS AND PPM-DOTS SERVICE PROVISION

The NTP uses the PPM-DOTS strategy to increase access to and use available TB and TB-HIV treatment, care and support resources in the private health sector. Hence the private sector may engage in TB control and prevention activities with PPM-DOTS whenever private health facilities come to an agreement with the RHBs by signing an MOU prepared by the NTP and the FMoH. (See Annex one for a template).

8.1 Documentation of Memorandum of Understanding

To determine whether a private DOTS provider is permitted to provide the service according to the NTP standards; all PPM-DOTS sites must have a copy of the signed MOU in the TB DOTS clinic for regulatory purposes. Upon discontinuation of the designated TB services, the facility must return the signed MOU to the RHB.

8.2 Supply and handling of TB drugs and reagents

In PPM-DOTS, handling of TB drugs is allowed for health professionals with IPLS training. The storage, recording and reporting of the drugs will be according to the National Pharmaceutical Standards.

8.3 Staffing and trainings

All PPM-DOTS clinics must have appropriately trained health professionals at all times for direct administration and follow-up of patients in the program as per the program standard.

8.4 Recording and reporting

Any PPM health care facilities should keep records of all relevant patients' data on the national TB registers and forms and report according to the NTP procedures. Ensure that PPM health care facilities are reporting to the respected administrative body during the reporting period.

8.5 Regulatory issues related to PPM-DOTS services

The national program will provide all the standards and requirements for selection and implementation of PPM-DOTS program in private facilities. The regulatory body in turn needs to:

- Participate in the process of facility identification, assessment and selection for PPM-DOTS program and ensure the proper implementation of the criteria while selecting new sites
- Be informed about the profiles of trained personnel from private health facilities
- Be communicated of any MOU entered into between the RHB and the private facilities for certification purposes
- Conduct regular inspection to ensure the program is running according to the MOU and the necessary standards are fulfilled as in the PPM-DOTS Implementation Guidelines
- Be informed with sufficient time lag for patient transfer and safe handover if the clinic is closing.

9. ADVOCACY, COMMUNICATION AND SOCIAL MOBILIZATION FOR PPM INITIATIVE

As it is noted in different TB related documents, the acronym ACSM that represents the three key communication strategies: advocacy, communication (behavior change communication) and social mobilization is very commonly used by stop TB partnership. It is a cross cutting element and part and parcel of all TB programs and plays important roles in creating awareness at all levels to ensure high level commitment; initiating and implementing TB control initiatives including PPM and influence all forms of health providers in engaging TB care activities.

Advocacy, one of the three key communication strategies focuses to improve political will and support the health service management at levels; it has roles to play in the improvement of accountability and responsiveness of service providers and participation of PPM health care facilities. Advocacy encourages all relevant health care providers to work closely with public health facilities in TB prevention and control. Advocacy did not only improve acceptability of the TB program in the PPM health care facilities but also motivate national TB control program staff to work together.

On the other hand, behaviour change/program communication aims at increasing knowledge, bring about attitudinal changes and promote practice among various groups of people. This is done by creating awareness about TB, improving interpersonal communication between patients and providers and empowering people to take actions. It frequently informs the public of the services that exist for diagnosis and treatment and relays a series of messages about the disease such as “seek treatment if you have a cough for more than two weeks”, “TB is curable” or informing the public about what services exist. It also creates an environment in which all forms of health care providers feel attracted towards providing correct TB diagnostic and treatment services. Behaviour change/program communication creates appropriate demand for TB care so that communities use public as well as private health care facilities that follow the guidelines set according to national and international standards and helps the national TB control program to achieve

its targets on improving diagnosis and treatment and reducing TB related mortality, incidence and prevalence. Behavior change communication in the context of PPM is to inform people that high-quality TB care services are also available at PPM health care facilities. The messages should explore the reasons why people do or do not take action on the information they receive, then focus on changing the actual behavior by addressing the causes identified – social norms or personal attitudes. The strategies should therefore focus on the specific issue and activities and messaging should be focused on addressing the main barrier to health-seeking behavior.

The third key communication strategy, social mobilization is important to create community will and commitment to participate in TB control and prevention within the context of the community. Social mobilization empowers people with or affected by the disease to take actions and enhances participation for sustainability and self-reliance. Major target audiences of social mobilization are communities, religious leaders and social networks. Hence, the frontline health workers including health extension health workers should educate households and the community on opportunities they can avail under PPM.

Therefore, the ultimate goal of ACSM is achieving behavioral and social changes depending on local context, which will contribute to sustainable improvement in TB case detection and treatment adherence, increase TB cure rate, reduce the risk of MDR-TB, decrease mortality due to TB and finally improve the quality of life of the people

10. MONITORING AND EVALUATION

Establishing a reliable monitoring and evaluation system is vital to monitor the contribution of PPM health care facilities towards the national TB prevention and control program. Recording and reporting of TB services with standardized tools helps to systematically monitor and evaluate the progress of patient/s and treatment outcome as well as the overall program performance.

10.1 Monitoring the performance of PPM health care facilities: PPM health care facilities must be considered the same as any public DOTS provider, and the local health officials should regularly monitor and provide all the necessary technical support accordingly.

10.2 Supportive supervision: The overall aim of supportive supervision is the promotion of continuous improvement in the service provision and program performance. It consists observation, discussion and provision of support and guidance. It is an important tool for proper implementation and assurance of quality of care in PPM health care facilities. Regular program supervision should be carried out to address the quality of information and to address performance problems. Both joint supportive supervision (JSS) and integrated supportive supervision (ISS) should be conducted at all levels. After each supervisory visit the supervisory team has to discuss strengths, weaknesses and problems identified, and recommendations with the PPM health care facilities and responsible local health office staffs. The finding generated from the supervision should be used for improving the performance of the PPM sites and/ or for decertification if the facilities did not abide with the MOU and did not provide the service as per the national standard.

10.3 Review meeting: It should be organized at various levels to review the program implementation status, achievements and challenges, and develop practical solutions for identified problems and challenges. Furthermore, review meetings are forums for exchanging ideas and experiences among the health professionals and program coordinators. Review meeting should be carried out regularly with the involvement of different stakeholders and local health offices should always invite PPM health care facilities while organizing TB program review meetings.

10.4 Recording and reporting: TBL and TB/HIV prevention and control program has standardized registers to record patients' information and to systematically monitor and evaluate progress of patients' treatment response and their treatment outcome. The registers and reporting formats of TB and TB/HIV collaborative activities are integrated within the National Health Management Information System (HMIS) of the FMOH. PPM health care facilities should record all relevant information completely and correctly.

The reporting of TB and TB/HIV collaborative activities are integrated into HMIS. All forms and registers are standardized and in line with HMIS throughout the country. Local health offices should provide unique HMIS profile for PPM health care facilities engaged in TB care and control activi-

ties. And each PPM facilities are expected to compile and submit a complete report to the responsible health office on timely basis. Besides to show the real contribution of PPM facilities, all public facilities should properly document and report all referred cases to the public health facility by PPM sites for TB diagnosis or to initiate anti TB treatment.

10.5 Evaluation: In order to assess the effectiveness of PPM health care facilities' engagement and its contribution towards TB prevention and control program, period evaluation should be carried out at national and sub national level. Or else, it can also be integrated with the national review of TB program.

10.6 Key indicators for monitoring and evaluation of PPM: It is important to use a standard set of indicators to monitor the performance of the PPM health care facilities and the quality of the program in the PPM health care facilities. Measuring effectiveness of engaging PPM health care facilities in TB prevention and control should include indicators such as specific targets for case detection, quality of case management and treatment outcome of the PPM health care facilities.

Table 2: PPM health care facilities monitoring and evaluation indicators

Indicator	Definition	How to measure the indicator	Data source	Frequency
Proportion of private facilities providing PPM-DOTS	The proportion of private practitioners certified to provide PPM-DOTS	Numerator: Number of certified PPM-DOTS facilities Denominator: Total number of eligible private health facilities	Local health office's health service unit	Annually
TB Case Detection through PPM health care facilities	The percentage of all forms of TB patients diagnosed and notified with TB who were initially	Numerator: Number of TB cases (all forms) referred &/or diagnosed and on DOT through PPM health care facilities during the reporting	Unit TB register	Quarterly

Indicator	Definition	How to measure the indicator	Data source	Frequency
	referred by PPM health care facilities during report-ing period.	period Denominator: Total number of TB cases (all forms) registered during reporting period. Data Source: TB Unit Register and private health facilities report from HMIS system		
Treatment success rate of all forms of TB cases in the PPM-DOTS-sites	Rate all forms of TB cases who success-fully cured or completed treatment	Numerator: new all forms of TB cases successfully treated (all cured plus all completed) Denomi-nator: New all forms of TB cases regis-tered.	Unit TB register	Quarterly
Not evaluat-ed rate of all forms of TB cases in the PPM-DOTS sites	Rate of all forms of TB cases that are transferred out among the total registered cohort TB cases	Numerator: number of total trans-ferred-out TB patients Denominator: Total all forms of regis-tered cohort TB cases	Unit TB register	Quarterly
Lost to follow up rate among all forms of TB cases	The percentage of a cohort of all new forms of TB cases registered in a specified period that interrupted	Numerator: The number of all new forms of TB cases registered in the specific cohort period that interrupt-ed treatment for more than two consecutive months	Unit TB Register	

Indicator	Definition	How to measure the indicator	Data source	Frequency
	treatment for more than 2 consecutive months	Denominator: The total number of all new forms of TB cases registered during the same cohort period		
Death rate of all forms of TB cases in the PPM-DOTS sites	The percentage of a cohort of all forms of TB cases registered in a specified period who died during the treatment period, irrespective of the cause	Numerator; Number of all forms of TB cases registered who died during the treatment period Denominator: Total number of all forms of TB cases registered in the same cohort period.	Unit TB register	Quarterly
Drug Susceptibility Test (DST) coverage for TB patients	Percentage of Pulmonary TB (new and retreatment) cases and presumptive DR-TB cases with documented DST result during the reporting period during the specified period	Numerator: Pulmonary TB (new and retreatment) cases and presumptive DR-TB cases with documented DST result during the reporting period Denominator: Total number of Pulmonary TB (new and retreatment) cases and presumptive DR-TB cases in the same period number of cases eligible for drug susceptibility testing according to national policy during the same period	TB Unit Register	Quarterly

Indicator	Definition	How to measure the indicator	Data source	Frequency
RR/MDR TB cases detected	Number of MDR/RR-TB cases Detected during the reporting period.	Numerator :Number of MDR/RR-TB cases detected during reporting period Denominator: NA	TB Unit Register	Quarterly
HIV testing for TB patients	The proportion of TB patients enrolled in DOTS who have documented HIV test result	Numerator: The number of TB patients enrolled in DOTS who are tested for HIV in the quarter Denominator: The total number of TB patients enrolled in DOTS during the same period	TB Unit Register	Quarterly
Anti-Retro-viral Therapy (ART) for HIV positive TB patients	Proportion of HIV-positive TB patients who are started on or continue previously initiated ART during their TB treatment.	Numerator: All HIV-positive TB patients, registered over the reporting period, who Received ART (are started on or continue previously initiated ART). Denominator: Total number of HIV-positive TB patients registered during the reporting Period.	TB Unit Register	Quarterly
INH Preventive therapy (IPT) for HIV positive clients	Proportion of the total number of newly enrolled HIV-positive people started on IPT during the reporting period	Numerator: Number of HIV positive individual newly enrolled in HIV care who started on (are given at least one dose of) IPT during reporting period	Tally sheet in HIV and PMTCT unit	Quarterly

Indicator	Definition	How to measure the indicator	Data source	Frequency
		Denominator: Total number of IPT eligible HIV positive clients newly enrolled in to HIV care during the reporting period.		

10.7 Operational research

Operational research may be conducted to address specific questions related to the implementation of TB program in PPM facilities. NTP/FMOH should closely work with universities and partners in generating evidence on the implementation of PPM in TB care and control, such as cost-effectiveness of different approaches, equity in access, and identification of factors of success and sustainability.

11. REFERENCES

EPHI.2009. AFB microscopy manual, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.

EPHI.2009. Guideline for quality assurance of smear microscopy for Tuberculosis diagnosis, Ethiopian Public Health Institute, Addis Ababa, Ethiopia, 2009

FMOH.2015. Health Sector Transformation Plan, 2015/16–2020/21, Addis Ababa, Ethiopia.

FMoH.2014. Public Private Partnership in Health, strategic frame work for public private partnership in Ethiopia, Federal Ministry of Health, Addis Ababa, Ethiopia.

FMoH.2017a. National PPM action plan in Ethiopia 2016-2020, Federal Ministry of Health, Addis Ababa, Ethiopia.

FMoH.2017b. National Tuberculosis, Leprosy and TB/HIV Prevention and Control Program, Addis Ababa, Ethiopia.

FMoH.2017c. National guideline for TB, DR-TB and leprosy, Six Edition,Federal Ministry of Health, Addis Ababa, Ethiopia.

FMoH.2013. Implementation guideline for Xpert MTB/RIF assay in Ethiopia, Addis Ababa, Ethiopia.

TB CARE I. 2014. International Standards for Tuberculosis Care, third edition. TB CARE I, The Hague.

Wells WA, Uplekar M, Pai M .2015. Achieving Systemic and Scalable Private Sector Engagement in Tuberculosis Care and Prevention in Asia. PLoS Med 12(6): e1001842. doi:10.1371/journal.pmed.1001842

WHO.2014. The End TB Strategy: Global strategy and targets for tuberculosis prevention, care and control Geneva, Switzerland.

WHO Regional Tuberculosis Program.2004. DOTS in the African Region "A framework for engaging private health care providers", Harare, Zimbabwe.

WHO.2006. Engaging All Health Care Providers in TB Control, WHO/Stop-TB Partnership, Geneva, Switzerland.

WHO.2007. Public–Private Mix for TB Care and Control: A tool for national situation assessment, Geneva.

WHO.2017. Global TB Control Report 2017, Geneva, Switzerland.
WHO.2016. Global TB Control Report 2016, Geneva, Switzerland.

WHO.2010. Public-private Mix for TB Care and Control: A Toolkit, WHO/Stop-TB Partnership, Geneva, Switzerland.

12. ANNEXES

Annex12.1 Memorandum of Understanding between the XX-Health Bureau and the PPM Health Care Facilities

Operational agreement made on TB and TB/HIV service delivery between the XX Health Bureau (XX-RHB) and _____-Clinic/Hospital

Whereas: XX- Regional State inhabits an approximate total population of around __ million reflects has TB case detection of __% in 20__, with an annual average of ___new TB cases, TB being among the top 10causes of morbidity ,and the commonest opportunistic infection and leading causes of death in HIV patients.

Whereas: The XX-Health Bureau (hereafter referred as XX-RHB) is a lead organization of preventive, promotive as well as curative health service in the XX region by the powers and authority vested upon executive organs by Proclamation 120/1998 by XX- Regional State making great effort to expand its response to the prevention and control of TB, TB/HIV according to national standards strengthening the TB/HIV collaborative activities.

Whereas: The XX National Regional state Bureau Health has identified _____ to initiate provision of TB, TB/HIV services.

Whereas: _____ has shown willingness and is assessed and found to have fulfilled the minimum criteria of TB, TB/HIV service delivery as per the national TB/HIV implementation guide line.

Whereas: The XX Regional Health Bureau had provided relevant training on TB and TB/HIV, now therefore, the parties hereto agree as follows:

ARTICLE I
AGREED FUNCTION OF THE PROGRAM

The _____Health Bureau will:

1. Provide TB drugs free of charge with adequate shelf life and reliable supply.

2. Provide AFB reagents with sufficient amount; and will regularly refilling the supplies.

3. Provides formants and TB drugs to the service as per case load /or the schedule of the program.

4. Establish appropriate referral system with public and other private health facilities. XX-RHB together with Zonal Health Department and Town/Woreda Health Offices will assist private health facilities in receiving report on patients transferred out to public health facilities.

5. XX-RHB will strengthen private health facilities defaulters' tracing by networking with the Woreda/Town Health Offices. The private health facilities will inform their respective Woreda/Town Health Offices on the number of defaulters and other details that may help the Woreda/Town Health Office for defaulters' tracing.

6. Strives to avoid the shortage or interruption of TB drug supply and recording and reporting registers and formats.

7. Provide training on TB, TB/HIV to relevant health workers of the private health facilities.

8. Provide the health facility with relevant policy directives, standard management and treatment guidelines.

9. Conduct supportive supervision, monitoring and evaluation on the program activities; and provides stewardship to the whole program activities.

10. The bureau will take a leadership for working with regional laboratory for timely EQC sample collection from private health facilities; and the provision of timely EQC feedback to the private sectors.

ARTICLE II

AGREED FUNCTIONS OF PRIVATE HEALTH FACILITY Accredited for anti-TB/HIV

care_____

1. Maintain the minimum requirements for TB,TB/HIV service delivery as per the TB/HIV implementation guide line on clinical, pharmacy and laboratory minimum packages at all times.

2. Deliver the TB DOTS and TB/HIV service in an appropriate practice set up and patient flow design.
3. Ensure safety and proper management of drugs in the clinic.
4. Safeguard drugs or use the supplies provided to the facility not to be used other than the intended program.
5. Ensure timely ordering and reporting of TB drugs requirement to maintain stock availability and prevent intermittent drug supply.
6. Agree to return the drugs/supplies provided to the facility by the national control program, when interrupted the contract in providing the above mentioned services.
7. Agreed to establish appropriate and enabling information system for tracking patients upon defaulting if any, and provide reports of defaulters as early as possible to the respective town health offices.
8. Adhere to the national standard activity documentation, information storage and data compilation guidelines and timely report to the appropriate government health authority.
9. Receive guidelines, technical assistance, training and supportive supervision from XX-RHB or from a partner delegated by the XX-RHB to execute these activities.
10. Ensure safe handling of patients upon termination of the service before 6 months in communication with the XX-RHB(Respective Zonal and Woreda/Town Health Offices)

ARTICLE III
LIABILITY

1. Subject to the provision of this operational agreement both parties are liable to perform the functions specified on the agreement and any damage or demand arising out of malfunction or failure to perform the functions will be indemnified or be the sole responsibility of the doer of the action.

2. Complying with whole agreement and failure to adhere to the terms and conditions of this agreement will result in its cancellation.

ARTICLE IV
ENTRY INTO FORCE, REVIEW AND TERMINATION

This agreement:

1. Will enter into force and be effective where and when it is duly signed by the contracting parties and will remain effective for the unlimited period of time.

2. May be amended or terminated by exchange of note between the parties pursuant to the provision.

3. Disputes on interpretation of this agreement will be mutually solved with the view to successfully attain the goal and objectives of the implementation of the program.

In witness whereof the parties hereto intending to be bound by the term of this memorandum of understanding have executed the same in a manner agreeable to both parties hereby signed the agreement at place and on the day and year specified below.

For and behalf of XX-RHB
Name _____
Title _____
Signature _____
Place _____
Date _____

For and behalf of the_____
Name _____
Title _____
Signature _____
Place _____
Date _____

Annex 12.2 TB-DOTS Drop-Outs/Lost-to-Follow-Up Patient Tracing Request Form

Date_____
No._____
Requesting Facility: _____
Town _____
Requesting To: _____Woreda/Town Health Office

Purpose of the request: - is to trace and link to treatment a patient whose information is stated below.

Patient's name and address

Name of the patient _____ Age _____ Sex _____

Town / woreda _____ Kebele_____

Telephone _____

Contact person's name and address

Name of the contact person _____

Telephone of the contact person _____

Clinical detail

Diagnosis _____

Treatment category _____

Date of treatment started_____

Last date a patient not attended his/her appointment

_____

Any effort made at facility level to trace the patient back to TB treatment?

_____

_____

_____

_____

_____

_____

_____

_____

Thank you in advance for partnership

Name of the health care provider:_____

Cell phone _____

Facility telephone: _____

Signature: _____

Annex 12.3 Standard Operating Procedures (SOPs) for Microscopy in PPM-DOTS

Local health managers, laboratory professionals and service providers with the necessary requirements to organize/set up TB smear microscopy laboratory in the private health sector need to consider all aspects of TB microscopic diagnosis including:

1) Human resources and Infrastructure of the lab
2) Work flow processes
3) Lab Quality Control
    a. QA
    b. IQC
    c. EQA
    d. Preventive Maintenance
    e. Lab safety
4) Recording and Reporting

Human resources and infrastructure of the lab

Personnel: In order to function properly, a laboratory must be adequately staffed. For optimum performance, the minimum number of employees required include: one or two laboratory technician or technologist for TB smears microscopy. A laboratory technician or technologist is essential to guarantee a high quality of routine services, and to implement the quality assurance activities for sputum smear microscopy. S/he should be a well-trained and knowledgeable about TB microscopy.

Infrastructure of the lab: Ideally, tuberculosis microscopy should be done in a separate room. However, tuberculosis microscopy services are usually integrated in general laboratory diagnostic services in most resource limited countries, which makes the design of a dedicated tuberculosis microscopy laboratory difficult. The following minimum requirement should be required to set up TB smear microscopy and in the provision of microscopic services in private health labs.

a) One well lighted area (preferably a separate room) with a min mum size of at least, 5 x 6 m2 in a private health setting with four tables

- one area for receipt of specimens
- one area for smear-preparation and staining
- one area for microscopic examination
- one area for laboratory registers

b) Electric power supply for microscopes

c) A sink with running water

d) A basin with a filter can and tap or siphoned plastic flask (in case there is no running water)

e) Four adjustable stools or chairs

f) A closed wardrobe or locker for storage and keeping gowns

g) Introduction of new TB Dx tools

The introduction of new and rapid techniques should be considered a key part of the PPM-DOTS initiative as it contributes to better TB case detection. Introduction of new technology will follow established national policy.

Work flow process

A. Specimen collection, preparation, staining of smear, examination and reporting and recoding of results: The TB microscopy laboratory's process of work flow consists of pre-examination, examination, and post-examination processes beginning with the collection of sputum specimens, preparation and staining of smear, microscopic examination, and reporting and recording of results.

All tasks in the process should be performed based on the national TB Microscopy Manual. In addition to TB Microscopy Manual, TB smears microscopy lab need to have standard operating procedures (SOPs) for operations in the TB microscopy work flow process. Current SOPs must be readily available in the work areas and accessible to testing personnel. The procedure described in the SOP must be followed exactly by all staff members to ensure high quality results. SOPs should also be written in a standard format, such as the format recommended by national Laboratory standard.

B. Sputum sample referral: Regional health bureau should link private health facilities providing TB microscopy to the national sample referral system for culture and drug susceptibility testing (DST) services. Safe packaging and transportation of sputum samples from the point of collection to the reference laboratory should follow the national standard along with instructions to be prepared for the preservation or handling of sputum samples.

Quality assurance of sputum microscopy

Accuracy and reliability of laboratory testing are critical to the success of TB control programs. All parts of the testing system must be monitored to ensure the quality of the overall process, to detect and reduce errors, and to improve consistency between testing sites. To ensure reliability and to reduce errors, a quality system must address all parts of laboratory testing. Therefore, quality assurance of acid fast bacilli (AFB) sputum smear microscopy is essential.

Quality Assurance (QA) is a system designed to improve the reliability and efficiency of laboratory services. WHO and the International Union Against Tuberculosis and Lung Disease (IUATLD) have defined several components for a quality assurance program for AFB smear microscopy:

- Quality Control (QC): A systematic internal monitoring of work practices, technical procedures, equipment, and materials including quality of stains.

- External Quality Assessment (EQA): A process to assess laboratory performance. EQA includes onsite evaluation of laboratories, panel tests, and blinded smear rechecking.

- Quality Improvement (QI): A process by which the components of smear microscopy diagnostic services are analyzed with the aim to identify and permanently correct any deficiencies. Data collection, data analysis, and creative problem solving are skills used in this process.

For laboratories performing sputum smear microscopy, QC should be conducted for the following areas of operations:

Laboratory arrangement and administration

- Ensure that doors into the laboratory are always closed.
- Work areas, equipment, and supplies should be arranged for logical and efficient workflow.
- Work areas should be kept free of dust. Benches should be cleaned at least daily with an appropriate disinfectant.
- Use laboratory procedures that comply with the National TB Program guidelines
- Every procedure performed in the laboratory must be performed in line with SOPs.
- Operating manuals/SOPs must be kept in the laboratory and be readily available.
- Any changes to procedures must be dated and initialed by the laboratory supervisor.
- Staff should have appropriate training and have their performance regularly monitored.

Laboratory equipment

- The operating manual and cleaning instructions for all equipment must be readily available.
- Dated service records must be kept for all equipment.
- Microscope and balance must be monitored regularly to ensure consistent performance.

Specimens and request forms

- Perform microscopy only upon written request of authorized persons. Do not allow oral requests without a follow-up completed request form.
- Insist on adequately completed request forms and proper labeling of specimens. This ensures positive identification of patients.

- Reject specimens that cannot be properly identified, are leaking, or are in broken containers; request a repeat specimen.

- Record the date all specimens arrive in the laboratory. Document any delays in the delivery of specimens to the laboratory on the request form.

- Evaluate the quality of sputum specimens. Record and monitor the number of salivary specimens received by the laboratory.

- Keep laboratory request forms separate from specimens.

- Forms that have been contaminated during transportation or otherwise by specimens should be discarded after autoclaving, burning, or burying. Accurately make duplicate form from the original form before discarding.

Staining reagents

- All staining reagents should be labeled with the name, date of preparation, and date first opened.

- If staining reagents are prepared in another laboratory, indicate the date received.

- Any material found to be unsatisfactory should be recorded as such. Remove this material from the laboratory immediately so it is not utilized.

- Limit stocks to six months' supply. Rotate stock to ensure that the oldest material is used first.

Staining and smear examination

- Filter carbolfuchsin regularly.
- Do not stain more than 12 slides at a time.
- Include positive and negative controls at least weekly.
- Read control slides before patient smears.

- Resolve any problems with control smears before reporting patient smears. Some problems may require repeating patient smears in a failed staining batch.

Recording and reporting

- Send microscopy results out as soon as they are available, preferably within 24 hours after the sputum specimen is received. Monitor any delays or turnaround time in delivery on the report form.

- Analyze microscopy results on a monthly basis to detect changes which may indicate a problem.

- All microscopy results must be recorded in standard format in the laboratory register.

- All records should be retained for at least two years.

EQA: Three methods can be used to evaluate laboratory performance:

- On-site evaluation
- Panel testing
- Blinded smear rechecking

On-site evaluation and blinded rechecking are the two methods most recommended by NTP for peripheral facilities.

Responsibilities of laboratory personnel for blinded rechecking include:

1. Storing slides in a way that allows retrieval of every slide identified for rechecking the sample. These must be stored in slide boxes in the same order as they are listed in the laboratory register. Two blank spaces should be left behind the first slide of a patient with suspected TB. This allows the second and third slides to be added after they are checked. This process will keep the results consistent with the laboratory register.

2. Label slides in a manner consistent with the laboratory register to ensure that the correct slide can be matched to the result. The labeling must be legible. The result of the smear examination must not appear on the slide.

3. Prior to placing slides in storage boxes, allow excess oil to drain off the slides and soak the oil by using paper (oil can be removed from smears by either gently placing face down on toilet tissue or wrapping in the tissue paper and leaving overnight). Store slides in boxes that allow the immersion oil to drip off. Slides should not touch each other (i.e. do not stack or press slides together).

4. Always store slides in closed boxes away from direct sunlight. It is not necessary to use xylene to remove oil from the slides.

The re-reading of positive smears by another technologist is highly desirable. Labs should store all examined sputum smear slides for blinded rechecking by the regional lab for EQA

Recording and reporting

The results of the smear examination should be reported on a standard report form and recorded on a lab register according to the national AFB microscopy laboratory manual grading scale as follows:

Examination finding	**Result recorded as**	**Laboratory result**	**No. of fields examined**
No AFB in 100 oil immersion fields	Negative	NEG	100
1 to 9 AFB in 100 oil immersion fields	Positive	1-9 (Scanty)	100
10-99 AFB in100 oil immersion fields	Positive	(+)	100
1-10 AFB per oil immersion field	Positive	(++)	50
> 10 AFB per oil immersion field	Positive	(+++)	20

All information from the laboratory form should be entered in the appropriate spaces of the laboratory register. All the information requested in the laboratory register must be entered, i.e., a blank space is not a negative result but a missing record. Positive results are entered in red ink.

PPM-DOTS microscopy centers conduct and record quality assurance on a daily basis through the sputum collections, smear preparation, staining to microscopic examination of AFB smear in accordance with the national quality assurance manual.

Safety precautions and disposal

Laboratory workers are responsible for their own safety and that of their co-workers and the community. Transmission of Mycobacterium tuberculosis results from micro-aerosols. Lab workers should follow national biosafety guidelines specific for TB microscopy laboratory. The environment in which laboratory testing is performed must be conducive to efficient operations that do not compromise the safety of the staff or the quality of the pre-analytical, analytical and post-analytical processes.

Laboratory work areas must have sufficient space so that there is no hindrance to the work or employee safety. All floors, walls, ceilings, and bench tops of the laboratory must be clean and well maintained. TB smear microscopy procedures within the laboratory that are not contained in closed systems must have a uni-directional work-flow.

Disposal of sputum specimen should be done as per the general Health Facility Infection Control Guideline and National Biosafety Guideline.

St.Paul's Hospital Millennium Medical College Printing Press